

### **REMARKS/ARGUMENTS**

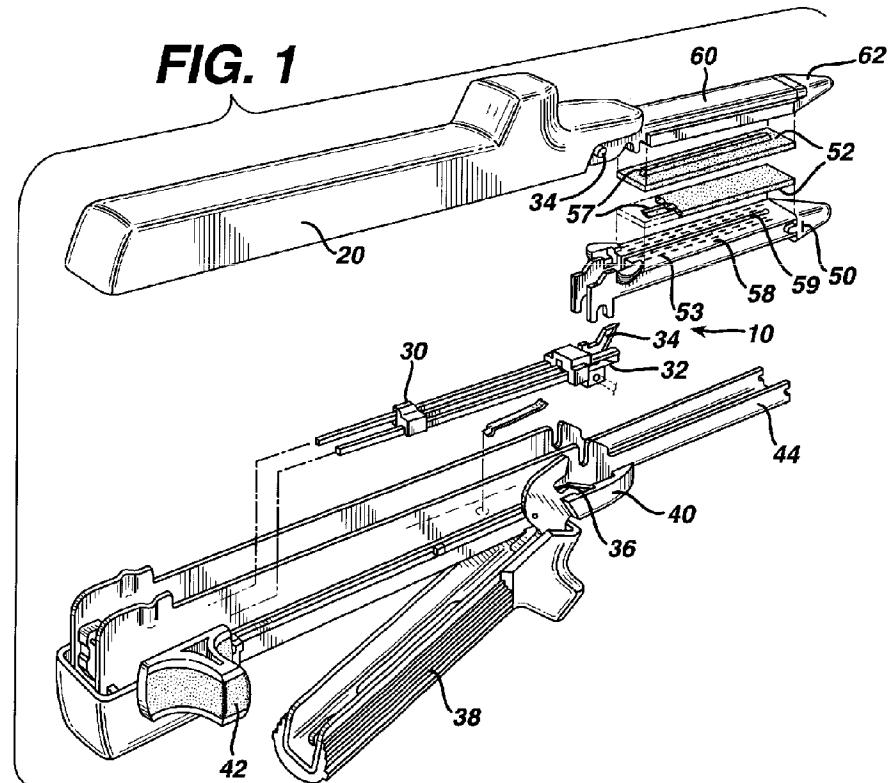
The foregoing amendments are made in response to the official action of June 18, 2007.

Claim 1 has been amended to clarify that the combination of the arteriotomy staple and pledget relates to an individual staple adapted for individual attachment, at its proximal end, to a single-staple delivery device, with the pledget being pre-attached to the staple and having surfaces frictionally engaged by and between the prongs of the individual staple to enable the combined staple and attached pledget to be advanced together by the delivery device toward the arteriotomy. Those limitations are present in each of the remaining claims by reason of their direct or indirect dependency from claim 1. Claim 49 has been amended to define with further particularity that the staple has four prongs. Dependent claim 50 has been added.

### **THE CITED PRIOR ART**

#### **U.S. Patent 6,273,897 (Dalessandro)**

The Dalessandro '897 patent describes a linear cutter stapling device by which a plurality of laterally spaced rows of staples are applied on opposite sides of a tissue cut. (1:11-17). The arrangement is illustrated in FIG. 1, reproduced below.



The stapler includes a pair of jaws 20, 40, one (40) of which is adapted to carry a staple cartridge 50 with at least two laterally spaced rows of staples (3:27-28). The other jaw 20 includes an anvil 60 with staple closing depressions in alignment with the rows of staples in the cartridge. (1:20-25). An elongate buttress 52 extends over the surface of the staple cartridge and another buttress 52 extends over the surface of the anvil 60. A knife 34 is advanceable longitudinally of the jaws to cut the tissue and the buttresses 52 after they have been stapled. The buttresses (pledgets) 52 are secured to the stapler. (1:46-47). Dalessandro '897 describes pledges that are "...releasably attachable to the staple cartridge and/or the anvil of a surgical stapling apparatus without conventional pins, clips, welds or adhesive." (1:56-59). To that end, the buttresses 52 are provided with longitudinally extending projections 57 that extend into longitudinal channels formed respectively in the cartridge and in the anvil to hold the buttresses 52 in a "releasable pressure fit" (3:40; 4:59-62).

After the tissue segments have been clamped between the buttresses by the jaws, the stapler is fired to drive the staples in the parallel lines of staples through the openings 53 in the cartridge. The staples pierce the buttresses and the tissue and the distal ends of the staples are formed to a B-shape or flat shape by engagement with the anvil. The knife 34 is advanced distally to cut the gripped tissue sections and buttresses between the parallel lines of staples. (7:22-45).

#### **U.S. Patent 5,634,931 (Kugel)**

Kugel discloses a hernia mesh patch adapted to be folded and inserted through a relatively small incision in the region of the hernia. The mesh device is configured to enable a sutureless repair. It is folded and advanced through the incision. Its structure facilitates manually positioning to cover the herniated region and certain of its surfaces are configured to help maintain the patch in place without fasteners. The position retaining elements include holes 59 (7:66-8:1). Other embodiments include projections 82, scalloped or fringed circumferential edges 88 to also hold the hernia mesh patch in place. (8:28-44). There is no disclosure in Kugel of any fastener of any kind, including sutures, staples or the like.

**U.S. Patent 5,366,479 (McGarry)**

The McGarry patent is said to disclose a surgical staple adapted to attach surgical mesh to body tissue in laparoscopic hernia surgery. The staples are said to be stored in stacked relationship at the distal end of an endoscope means (3:5-6; 9:60-61). A staple storing magazine 16 is adapted to contain a plurality of the staples which are particularly shaped to penetrate and to attach surgical mesh to body tissue. (16:42-47). A staple is configured to be used in conjunction with a specific stapler by which arcuate portions of bridge portions of the staple cause the staple legs to fold inwardly toward each other with one leg crossing over the other. (19:41-47).

**CLAIM REJECTIONS – 35 U.S.C. §102**

Reconsideration is requested of the rejection of claim 1 as anticipated by Dalessandro '897. Claim 1, as amended, is directed to an arrangement of a combined individual staple and plegget by which the plegget is pre-attached to the staple, with the plegget having surfaces that are frictionally engaged by and between the prongs of the staple such that the combined staple and attached plegget can be advanced together by a single-staple delivery device. The staple and plegget are configured for use in closing an arteriotomy.

Dalessandro does not disclose the claimed staple and plegget arrangement. Dalessandro discloses a stapling arrangement in which two groups of staple rows are attached simultaneously to tissue. There is no disclosure of an individual staple and pre-attached plegget adapted for individual attachment to a single-staple delivery device. Dalessandro discloses a very different device in which plural staples are applied together through tissue and buttress strips that are attached to the stapler and then are severed. In Dalessandro the pleggets are not pre-attached as in applicants' claim but, instead, are detachably mounted to each of the stapler jaws.

Reconsideration also is requested of the rejection of claims 5-17 as anticipated by Dalessandro. Each of those claims depends directly or indirectly from claim 1 and is not anticipated by Dalessandro for the same reasons.

**CLAIM REJECTIONS – 35 U.S.C. §103**

Reconsideration is requested of the rejection of claims 3, 4 and 48 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Dalessandro '897 and Kugel '931.

To the extent that the rejection is based on the notion that Dalessandro discloses the claimed arrangement except for the pledget, that is incorrect as discussed above in connection with the rejection of claims 1 and 5-17. Kugel fails to disclose those features of applicants' claimed invention that are missing from Dalessandro. Kugel does not disclose any kind of a pledget. Kugel merely discloses a hernia mesh patch that is configured so that it can be shaped to a small size, placed by the physician, manually, through a small incision, and then expanded. The objective of the Kugel patch is that it can be retained in its placed position without sutures. There is no disclosure or suggestion at all in Kugel of the use of any kind of fastener, much less a staple. To the contrary, the objective in Kugel is to avoid using fasteners. Kugel has nothing to do with arteriotomy closures or with any kind of stapling devices. In the absence of any explicit reason and analysis in demonstrating a basis for their combination, the §103(a) rejection based on Kugel and Dalessandro is improper and constitutes hindsight reasoning. Indeed, where Kugel's objective is to avoid the use of fasteners that would teach away from using Kugel with fasteners such as staples.

Additionally, claim 3 includes the further limitation that the pledget comprises a plurality of peripherally extending tabs configured to be received between the plurality of prongs. There is nothing in Kugel to suggest that the tabs 62 serve any function relating to staples. With respect to claim 4, the same applies to the holes 59. Both the tabs 62 and holes 59 are not adapted to receive staple prongs but simply are to provide surfaces to engage tissue so that the device can be placed manually and held in place without any additional securing fasteners. The rejection based on the combination of Kugel and Dalessandro relies on a hypothetical combination, apparently prompted by applicants' claims, without any stated reason for making that combination. Indeed, where the holes 59 also are intended to allow in-growth of scar tissue (7:66-8:3), the presence of staple prongs in holes 59 would seem to prevent such tissue in-growth, impairing the ability of Kugel to achieve its intended function.

Reconsideration also is requested of the rejection of claim 49 under 35 U.S.C. 103(a) in view of the combined disclosures of Dalessandro and McGarry '479. As discussed above, Dalessandro does not disclose the claimed device and McGarry fails to disclose those features of applicants' invention, as discussed above in connection with claim 1, that are missing from Dalessandro. Additionally, claim 49 has been amended to further clarify that the staple has four prongs. The prongs are connected at their proximal ends to the crown. Neither of Dalessandro

or McGarry disclose a four-prong staple and crown. Moreover, McGarry and Dalessandro are conceptually incompatible because of the manner in which the McGarry staple is intended to be closed (with its staple legs being crossed). The combination of Dalessandro and McGarry is considered to be improper.

**The §103(a) Rejections Are improper Because They Do Not Resolve and Articulate The Level of Skill That Was Applied**

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The rejections under 35 U.S.C. §103(a) also are improper because they fail to resolve and articulate the level of ordinary skill in the art that was applied. One of the essential underlying factual elements that must be determined under the Supreme Court decisions of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) is that the level of skill must be resolved. The action fails to indicate what level of skill was applied in the §103(a) rejections. That failure leaves no basis to test the correctness of the rejection. The failure to articulate the level of skill is, itself, a basis for withdrawal of the rejection.

Respectfully submitted,

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